

AUG 15 2002

SURGICON, INC.  
510(k) NOTIFICATION

K021747

## 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER Surgicon, Inc.  
400 Long Beach Blvd. – Stratford, CT 06615

CONTACT PERSON Curt Raymond

DATE PREPARED May 21, 2002

CLASSIFICATION Accessory to laparoscope

COMMON NAME Laparoscopic specimen container

PROPRIETARY NAME DeGall Laparoscopic Gallbladder Extractor

PREDICATE DEVICES Auto Suture Endo Catch Specimen Pouch  
Minogue Xtractor Specimen Retrieval

DEVICE DESCRIPTION The device consists of an introducer and a polyurethane specimen container into which the excised gallbladder is placed. The device, with the specimen held within, is then withdrawn through the abdominal access wound (previously created by the trocar). The device can operate through a variety of access port sizes down to 5mm. The device is manually powered and controlled. It is composed of biologically safe materials. It is supplied sterile and intended for single use only.

INTENDED USE The subject device is intended for the retrieval and removal of the gallbladder in laparoscopic cholecystectomies.

TESTING The device has been subjected to in-vitro and in-vivo testing which demonstrate the ability of the device to withdraw and contain specimens under conditions in excess of those encountered during normal clinical use.

DEGALL\* LAPAROSCOPIC GALLBLADDER EXTRACTOR  
\* = ADVERTISED NAME/TRADE NAME

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 15 2002

Surgicon, Inc.  
Curtis Raymond  
Director, Regulatory & Quality  
400 Long Beach Boulevard  
Stratford, Connecticut 06615

Re: K021747

Trade/Device Name: DeGall Laparoscopic Gallbladder Extractor  
Regulation Number: 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: GCI  
Dated: May 24, 2002  
Received: May 28, 2002

Dear Mr. Raymond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

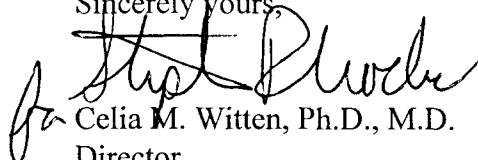
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Curtis Raymond

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address  
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



The signature is handwritten in black ink. It appears to start with a large 'f' or 'C', followed by a stylized surname.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

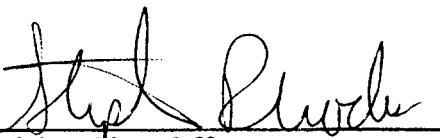
Enclosure

SURGICON, INC.  
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**STATEMENT FOR INDICATIONS FOR USE**

The subject device is intended for the retrieval and removal of the gallbladder in laparoscopic cholecystectomies.



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K021747

DEGALL\* LAPAROSCOPIC GALLBLADDER EXTRACTOR  
\*TM TRADEMARK NAME TENTATIVE

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